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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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Jerome Soupe

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ALSTON & BIRD LLP
BANK OF AMERICA PLAZA
101 SOUTH TRYON STREET, SUITE 4000
CHARLOTTE, NC 28280-4000

EXAMINER

TSAY, MARSHA M

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 08/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/519,131

Applicant(s)

SOUPPE, JEROME

Examiner

Marsha M. Tsay

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1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-40 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- 1) ☒ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. ____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

Claims 1-40 are pending and currently under examination.

Priority: The benefit date is July 2, 2002, for the purpose of prior art.

Specification

The disclosure is objected to because of the following informalities: on page 1, the priority data needs to be updated; on page 9, line 6, the metal ions Ca^+ and Mg^+ should be corrected to Ca^{2+} and Mg^{2+} .

Appropriate correction is required.

Claim Objections

Claim 13 is objected to because of the following informalities: the metal ions Ca^+ and Mg^+ should be corrected to Ca^{2+} and Mg^{2+} . Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 38 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites BV, and SV, and LV are parameters denoting ratios pertaining to the elution process. The definitions should be disclosed in the specification rather than in the claim because their recitation in the claim renders the claim as more confusing because the claim is really drawn to a process of isolating milk proteins from milk comprising unique steps. Furthermore, the claim recites the variables BV_f , SV_f , LV_f , BV_e , and LV_e . It is unclear what these parameters are because they are not disclosed and/or defined in the specification.

Claims 2-7, 10, 12-22, 28-30, 33-35, 37, 39-40 are included in this rejection because they are dependent on claim 1.

Claim 8 recites the variables BV_f , SV_f , and LV_f . The claim is indefinite because it is unclear what these parameters are because they are not disclosed and/or defined in the specification.

Similarly, claim 9 recites the variables BV_f , SV_f , LV_f , BV_e , and LV_e . The claim is indefinite because it is unclear what these parameters are because they are not disclosed and/or defined in the specification.

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Claim 11 recites the variables BV_e and LV_e . It is unclear what these parameters are because they are not disclosed and/or defined in the specification.

Claims 8-9, 11 are rejected because of the range within range, i.e. broad limitation followed by a narrow limitation. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. See MPEP § 2173.05(c). Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claims 8-9, and 11 recite a narrower range limitation for the broad recitation that is recited in the parent claim. The claims recite narrower ranges and/or limitations for the BV_f , SV_f , LV_f , BV_e , and LV_e parameters.

Claims 23-24 recite a pH in solution at 2% of between 6 and 7.5 and of between 6 and 7.2, respectively. It is unclear how the pH of a solution can be at 2% between two different pH levels.

Claim 25 is drawn to a milk protein fraction; however, the language of the claim render is confusing and renders the claim indefinite.

Claim 26 is included in this rejection because it is dependent on claim 25.

Claim 27 recites ABTS units. The claim should clearly define ABTS is 2,2¹-azino-bis-(3-ethyl benzo thiazoline 6-sulfonic acid).

Claim 31 is drawn to a food composition comprising a milk protein fraction. However, as currently written, the claim is incomplete.

Claim 32 recites the limitation "powder of milk protein fraction" in the claim. There is insufficient antecedent basis for this limitation in the claim and its parent claim.

Claim 36 is drawn to a pharmaceutical composition comprising at least one milk protein fraction and a pharmaceutically acceptable carrier. However, as currently written, the claim is incomplete.

Claim 38 provides for the use of a milk protein fraction, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31, 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Takada et al. (US 5976597; IDS). Takada et al. teach a basic protein composition is obtained from milk (col. 2 lines 45-60). In working example 8, Takada et al. teach a tablet comprising the basic protein composition and a pharmaceutically acceptable carrier (col. 9 line 35; claim 36) and in working example 11, Takada et al. teach a cracker comprising the basic protein composition (col. 10 line 27; claim 31).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-30, 32-35, 37-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takada et al. (US 5976597; IDS) in view of Kussendrager et al. (US 6010698; IDS). Takada et al. disclose a milk-derived basic protein composition can be obtained by passing milk or raw material through a cation exchange resin column (col. 2, line 55). In reference example 1, Takada et al. disclose non-sterilized skim milk was passed through a sulfonated chitopearl cation exchange resin at a flow rate of 25 mL/min. (col. 4 line 30). The column was washed with deionized water and phosphate buffer (pH 7.0) containing 0.1M sodium chloride to remove unadsorbed protein (col. 4

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line 35). The basic protein adsorbed on the resin was eluted with a 0.1-1.0M sodium chloride gradient pH 7.0 (col. 4 line 37-38). A reverse osmotic membrane was used to desalt and concentrate the eluted solution, followed by lyophilization, to obtain a powdery basic protein fraction (col. 4 lines 40-43).

Kussendrager et al. also disclose a process for recovering one or more proteins from milk comprising adsorbing at least one protein from the milk to a cation exchanger, followed by fractionated elution of the cation exchanger (col. 2). Kussendrager et al. also disclose it is highly advantageous to strip the starting milk material of fat before subjecting it to the adsorption and elution steps (col. 3 lines 10-15). According to Kussendrager et al., it has been found that after defatting, the cation exchange column is less clogged up during the adsorption step; therefore, preventing undue pressure buildup in the column and unfavorable shortening of the adsorption cycles (col. 3 lines 10-15). The defatting step can be carried out by microfiltration, with filter openings between 0.1 and 10 μm (col. 3 line 20). Kussendrager et al. disclose that it is preferred the cation exchanger has a mean particle size in excess of 100 μm , or 100-300 μm as to allow the cation exchanger to resist high liquid loads while also maintaining binding capacity (col. 3 line 25-30). Further, it is disclosed that the adsorption is carried out at a temperature lower than 10°C so as to keep any microbial growth to a minimum (col. 3 lines 40-42). Additionally, Kussendrager et al. disclose the starting milk material is pumped at a velocity of more than 500 cm/hr and at a high liquid load of 100-600 bed volumes/hr (col. 3 line 45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include the initial step of desterilizing the raw milk material of Kussendrager et al. to the process of isolating a milk-derived basic protein composition by passing milk through a sulfonated chitopearl cation exchange resin of Takada et al. wherein the milk fraction is eluted with aqueous salt solution, filtered using an ultrafiltration membrane, desalted, and followed by lyophilization to obtain a powdery basic protein fraction according to Takada et al. (claims 1-6, 8-9, 11, 13-22). The motivation to do so is given by Kussendrager et al. which teach that it is highly advantageous to perform a defatting step because the cation exchange column is less clogged up during the adsorption step; therefore, preventing undue pressure buildup in the column and unfavorable shortening of the adsorption cycles.

It would also have been obvious to one of ordinary skill in the art at the time the invention was made to use the cation-exchanger with a mean particle size of 100-300um and to maintain the column at a temperature of 10°C during conditioning and elution of the column as disclosed by Kussendrager et al. to the process of isolating a milk-derived basic protein composition by passing milk through a sulfonated chitopearl cation exchange resin of Takada et al. wherein the milk fraction is eluted with aqueous salt solution, filtered using an ultrafiltration membrane, desalted, and followed by lyophilization to obtain a powdery basic protein fraction according to Takada et al. (claims 1-7, 8-10, 11, 12, 13-22). The motivation to do so is given by Kussendrager et al. which teach that a cation exchanger having a mean particle size in excess of 100 um

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is able to better resist high liquid loads while maintaining binding capacity and that maintaining the column at 10°C or lower will keep microbial growth to a minimum.

While Takada et al. does not disclose the elution parameters as recited in the instant claims, these elements are believed to be unpatentable over Takada et al. in view of Kussendrager et al. because the method of Takada et al. in view of Kussendrager et al. is the same as the instant process, which is a process for isolating milk proteins from milk comprising: (a) sterilizing a raw milk material; (b) passing the desterilized milk fraction over a cation-exchange resin grafted by sulfonate functional groups; (c) eluting the adsorbed protein fraction with aqueous salt solution; (d) desalting the eluate or purified milk product by ultrafiltration and/or diafiltration.

Claims 23-30, 32-35, 37-40 are directed to a milk protein fraction and compositions comprising the milk protein fraction, respectively. As noted above, even though the specifics of the instant invention(s) are not explicitly spelled out by Takada et al. in view of Kussendrager et al., said specifics are obvious because slight variations in steps recited in the 103 method of Takada et al. in view of Kussendrager et al. leads to the instantly claimed methods and inevitably its final product(s).

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

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A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 35 and 39 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 34 and 37. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Jon Weber can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should

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you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

August 18, 2006

A handwritten signature in black ink, appearing to be "M. Monshi".


MARYAM MONSHIPOURI, PH.D.
PRIMARY EXAMINER